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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,938	03/08/2005	Yasuo Suda	12480-000104/US	7567

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EXAMINER

HAQ, SHAFIQUL

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.



## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121 and 372:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-14 and 18-28, drawn to drawn to linker compounds and ligands.

Group II, claim(s) 15-17, drawn to drawn to a method for measurement of surface plasmon resonance.

2. The inventions listed in groups I and II do not relate to a single general inventive concept under PCT rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reason : Invention group II does not contain as a special technical feature the preparation of a sensor chip from the **multi-branched linker compound** described in claims 1-3 of invention group I or the ligand set forth in claims 4-7 of invention group I. Therefore, invention group II does not share the same special technical feature with the invention group I.

Therefore, invention groups I and II are not so linked as to form a single general inventive concept.

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3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).
4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(1)
5. During a telephone conversation with Donald J Daley on 12/12/05 a provisional election was to prosecute the invention of Group I, claims 1-14 and 18-28. Affirmation of this election must be made by applicant in replying to this Office action. Claims 15-17 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

#### ***Status of Claims***

6. Claims 15-17 are withdrawn from consideration pursuant to 37 C.F.R. 1.142 (b) as being drawn to a non-elected invention.
7. Claims 1-14 and 18-28 are examined on merits.

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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2. Claims 1-5, 8-14, 18, 21-23 and 27-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claim 1 recites the term "versatile linker compound". It is not clear what is meant by this term. Versatile means "having great diversity or variety". Is the term meant for variety of linker compounds? The linker compound as understood from specification, is used to introduce sugar for detecting biomolecules that interacts with sugar molecules. It is not clear how the term "versatile" fits with the linker compound that collects only sugar molecules and interacts only with sugar specific biomolecules.
4. Claim 1 recites the phrase "multi-branched structure moiety including four hydrocarbon derivative chains". It is not clear how the hydrocarbon derivative chain is arranged or branched at "X". The chemical nature and structure of the hydrocarbon derivative chain is also unclear.
5. The term "may or may not" in line 7 of claim 1 renders the claim indefinite because the term "may or may not" is not a positive recitation as the term implies that the "carbon nitrogen bond in the backbone" is not a required component of the claimed invention.
6. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: protecting steps, condensation steps and deprotecting steps.

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7. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: steps for reductive amination reaction.
8. Claims 10, 18 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: steps for introducing sugar molecules.
9. Claims 13, 21 and 28 provide for the method of using the ligand carrier for surface plasmon resonance measurement, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.
10. Claims 14, 22 and 27 provide for the method of using the ligand carrier in affinity chromatography, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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12. Claim 1-5, 9-14 and 28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for hydrocarbon derivative chain comprising C-C bond, C-N bond, CO-NH bond and an aromatic amino group, do not reasonably provide enablement for all hydrocarbon derivative chains represented by the bond as defined in the specification (page 5, lines 11-30). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The term "hydrocarbon derivative chains", as defined in specification consists is a hydrocarbon chain, having an aromatic amino group at an end thereof, part of whose C-C bond serving as backbone structure of the hydrocarbon chain, may be replaced with a C-N, a C-O and an amide bond (page 5, lines 11-30). This definition encompasses many backbone structure including poly-ethylene oxide (PEG).

The specification provides guidance and working examples for linker compounds having hydrocarbon derivative chains comprising aromatic amino group at an end, and backbone structures comprising C-N bonds and amide bonds for linker compounds but there is no enablement in the specification for use of all other backbone structures (e.g. containing poly-ethylene oxide. PEG). As for example, PEG having an aromatic amino group at the end will not be able to produce branched structure (e.g. four PEG chain branching out from X) unless there is a nitrogen atom attached to carbonyl (i.e amide bond) group of formula (1) of claim 1.

***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 1-14 and 18-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayashi et al (Tentative Lecture Proceeding, Chemical Society of Japan 2001) in view Sumida et al (JP 2002-80488 A) and Tomalia et al (US 5,714,166).

Hayashi et al. disclose a linker compound wherein a branched structure containing two hydrocarbon derivative chain having a terminal aromatic amino group is bonded to a biotin terminal (see compound 1). Saccharides (e.g. heparin partial disaccharide structure (G1cNS6S-IdoA2S)) are then linked to amino group attached to benzene ring by reductive amination reaction to prepare compound 2 ligand. Hayashi et al also disclose that by taking advantage of the strong biotin-streptoavidin affinity, compound 2 was arranged on a surface of a sensor chip having streptoavidin immobilized thereon and a surface plasmon resonance measurement method for detecting interaction of saccharides using said ligand is also disclosed.

Hayashi et al disclose two hydrocarbon derivative chain in a branch chain structure. Hayashi et al., however, do not disclose four hydrocarbon derivative chains in a branched chain structure as claimed in present application.

Sumida et al disclose a ligand having oligosaccharide/phenylene diamine complex compound. This reference disclose that three to five hydrocarbon derivative



chains having saccharides bonded to terminal aromatic amino groups may be provided (see abstract and pages 1-7) and both the references of Hayashi and Sumida share the common feature that they both have same hydrocarbon derivative chain structure, and have a ligand structure capable of collecting oligosaccharide chains and a person skilled in the art would easily understand that increasing the hydrocarbon chain having terminal aromatic amino group in the linker compound would enable the collecting of saccharides to be carried out more efficiently.

Tomalia et al in a method of producing targeted dendrimer conjugates disclose that symmetric starburst polymer (e.g. PAMAM) having polybranched arm gives significant advantages which can provide a means for the delivery of high concentrations of carried materials per unit of polymer (column 1, lines 38-42) and disclose that branching can be increased at terminal amino group on a preceeding generation branch (see PAMAN in column 28 and branching strategy in column 30, G=1 and G=2 and G=3 in column 31). Tomalia et al also disclose protecting and deprotecting steps to protect amino groups and deprotect for reaction to occur. Tert-butoxycarbamate is preferred protecting group which can be deprotected by mild acid hydrolysis.

Therefore, given the above fact that increasing the number of derivative chain is advantageous for concentrating and detecting interacting biomolecules (Yomalia et al) and branch chain can be increased at amino terminal group (Yomalia et al), it would have been prima facie obvious to one of ordinary skill in the art at the time of the instant invention to increase the derivative chain of Hayashi et al., from 2 to 4

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from the teaching of Sumida et al, with the expectation of producing similarly useful linker compound. The method steps of claim 8 would be obvious considering that protecting and deprotecting steps for amino groups are well known in the art (Tomalia et al) and protection of aromatic amino groups using well known protecting group (e.g. t- butoxycarbamate) before attaching biotin molecule is inherently present in the reaction step for generating the reference compound of formula 1 (Hayashi et al).

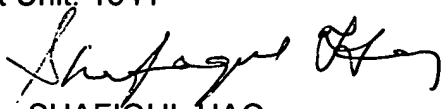
### ***Conclusion***

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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12/27/05